

RECEIVED
CENTRAL FAX CENTER

SEP 01 2005

MARTIN & FERRARO, LLP
1557 Lake O'Pines Street, NE
Hartville, Ohio 44632

Telephone
(330) 877-0700

Facsimile
(330) 877-2030

FACSIMILE TRANSMITTAL

TO:

Name: Mail Stop APPEAL BRIEF-Patents
Group Art Unit 3764

Firm: U.S. Patent & Trademark Office

Fax No.: 571-273-4702

Subject: U.S. Patent Application No. 08/354,450
Gary Karlin Michelson, M.D.
Filed: December 12, 1994
DEVICE FOR ARTHROSCOPIC MENISCAL
REPAIR

Attorney Docket No. 101.0023-04000

Customer No. 22882

Confirmation No.: 3041

FROM:

Name: Thomas H. Martin, Esq.

Phone No.: 330-877-2277

No. of Pages (including this): 25

Date: September 1, 2005

Confirmation Copy to Follow: NO

Message:

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that the attached Transmittal Form (in duplicate) and Reply Brief are being facsimile transmitted to the U.S. Patent and Trademark Office on September 1, 2005.


Sandra L. Blackmon

If there is a problem with this transmission please call Sandy Blackmon at 330-877-1202 or the sender at the number above.

The information contained in this facsimile message is privileged and confidential information intended only for the use of the addressee listed above. If you are not the intended recipient or the employee or agent responsible to deliver this message to the intended recipient, please do not use this transmission in any way, but contact the sender by telephone.

SEP 01 2005

PATENT
Attorney Docket No. 101.0023-04000
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson

Serial No: 08/354,450

Filed: December 12, 1994

For: DEVICE FOR ARTHROSCOPIC
MENISCAL REPAIR

Confirmation No.: 3041

Art Unit: 3764

Examiner: D. DeMille

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is a Reply Brief in response to the Examiner's Answer dated July 1, 2005 in the above-identified application.

- ☒ Applicant claims small entity status under 37 C.F.R. §§ 1.9 and 1.27.
- ☒ No additional fee is required.
- ☐ Applicant hereby requests a ***-month extension of time to respond to the above action.
- ☐ The total amount of \$*** to cover the above fees is to be charged to Deposit Account No. 50-1066.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1066. A copy of this sheet is enclosed.
 - ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
 - ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

Date: September 1, 2005

By: Todd M. Martin
Todd M. Martin
Registration No. 42,844

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (330) 877-0700
Facsimile: (330) 877-2030

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gary K. Michelson

Serial No: 08/354,450

Filed: December 12, 1994

For: DEVICE FOR ARTHROSCOPIC
MENISCAL REPAIR

Confirmation No.: 3041

Art Unit: 3764

Examiner: D. DeMille

Mail Stop Appeal Brief--Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is a Reply Brief in response to the Examiner's Answer dated July 1, 2005 in the above-identified application.

- ☒ Applicant claims small entity status under 37 C.F.R. §§ 1.9 and 1.27.
- ☒ No additional fee is required.
- ☐ Applicant hereby requests a ***-month extension of time to respond to the above action.
- ☐ The total amount of \$*** to cover the above fees is to be charged to Deposit Account No. 50-1066.
- ☒ The Commissioner is hereby authorized to charge any deficiencies of fees associated with this communication or credit any overpayment to Deposit Account No. 50-1066. A copy of this sheet is enclosed.
 - ☒ Any filing fees under 37 C.F.R. § 1.16 for the presentation of extra claims
 - ☒ Any patent application processing fees under 37 C.F.R. § 1.17

Respectfully submitted,
MARTIN & FERRARO, LLP

Date: September 1, 2005

By: Todd M. Martin
Todd M. Martin
Registration No. 42,844

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (330) 877-0700
Facsimile: (330) 877-2030

SEP 01 2005

PATENT
Attorney Docket No. 101.0023-04000
Customer No. 22882

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)	
Gary Karlin Michelson, M.D.)	
Serial No.: 08/354,450)	Group Art Unit: 3764
Filed: December 12, 1994)	Examiner: D. DeMille
For: DEVICE FOR ARTHROSCOPIC)	
MENISCAL REPAIR)	

Mail Stop APPEAL BRIEF-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF

Appellant submits the following reply to the Examiner's Answer dated July 1, 2005 (the "Examiner's Answer"). Appellant respectfully submits that the Examiner's Answer raised new grounds of rejection not designated as new grounds by the Examiner. Appellant is filing concurrently with this Reply Brief a Petition under 37 C.F.R. § 1.181(a) requesting the Commissioner to mail Appellant a corrected Examiner's Answer designating the new grounds of rejection as such.

Appellant submits the following remarks for consideration by the Board of Patent Appeals and Interferences.

I. General Remarks in Response to Examiner's Answer.

In the Examiner's Answer, the Examiner responded to many of Appellant's arguments set forth in the Appeal Brief dated April 20, 2005 (the "Appeal Brief") by improperly grouping together separate arguments made by Appellant and applying a single statement or rationale to the group of arguments. Despite the Examiner's grouping of Appellant's arguments, Appellant respectfully maintains that the claims do not stand or fall together except as otherwise indicated in the Appeal Brief.

The Examiner's Answer contains as many as 14 questions directed to the Board. Appellant submits that it is improper for the Examiner to ask the Board direct questions

Reply Brief 9-1-05.doc

in the Examiner's Answer. Appellant respectfully requests that the Board disregard these questions where they appear in the Examiner's Answer.

A. New matter objection and lack of support rejections.

1. Examiner's improper importation of prior art issues.

Throughout the portions of the Examiner's Answer related to the new matter objection and lack of written support rejections, the Examiner makes repeated references to the prior art. (See, e.g., Examiner's Answer, page 11, lines 13-20). Appellant respectfully submits that the Examiner's references to the prior art have no place in an objection to an amendment under 35 U.S.C. § 132 and rejections for lack of written support under 35 U.S.C. § 112, first paragraph. Issues concerning prior art involve wholly separate and distinct considerations. Appellant respectfully requests the Board to give no weight to the Examiner's statements about the prior art in deciding the new matter objection and the lack of written support objection and rejection.

2. Examiner's improper importation of a "criticality" standard.

The Examiner also makes repeated references to the need for "criticality" of certain limitations. (See, e.g., Examiner's Answer, objection to the specification under 35 U.S.C. § 112, first paragraph, page 6, paragraph 3). Appellant respectfully submits that criticality is not a requirement as to whether an amendment contains new matter, whether the claims are supported in the disclosure under 35 U.S.C. § 112, first paragraph, or whether the claims are indefinite under 35 U.S.C. § 112, second paragraph. Appellant respectfully submits that the Examiner's objection under 35 U.S.C. § 132, and rejections under 35 U.S.C. § 112, first and second paragraphs improperly include a criticality requirement which is not required by 35 U.S.C. § 132, and 35 U.S.C. § 112, first and second paragraphs.

3. No rationale is provided to support the objection and rejection of Appellant's method claims.

The Examiner's basis for the new matter objection and rejections under 35 U.S.C. § 112, first and second paragraphs is directed to Appellant's apparatus claims. No basis is provided to support the objection and rejection of method claims 273-292. Method claims do not require the same structural detail as apparatus claims in order to define a patentable invention. The Examiner's objection and rejection of method claims

273-292 do not contain any explanation as to what subject matter is considered to be new matter, or not supported by the specification. Therefore, the objection and rejections of claims 273-292 must be withdrawn.

Moreover, Appellant noted in the paragraph bridging pages 13 and 14 of the Appeal Brief that the Examiner had not provided any rationale for the rejection under 35 U.S.C. § 112, first paragraph specific to method claims 273-292. The Examiner acknowledged Appellant's observation concerning the lack of rationale specific to claims 273-292, but still failed to provide any rationale specific to these claims. (See Examiner's Answer, page 14, paragraph 4).

B. Prior art rejections.

1. 35 U.S.C. § 103(a) rejection in view of Warren.

The Examiner first rejected all of Appellant's independent claims under 35 U.S.C. § 103(a) in view of Warren. Second, the Examiner further rejected all of Appellant's independent claims under 35 U.S.C. § 103(a) over Bays in view of Warren. Appellant submits that the Examiner's use of Bays with Warren as a secondary reference in combination with Bays in a separate 35 U.S.C. § 103(a) rejection calls into question: (1) the appropriateness of asserting the second 35 U.S.C. § 103(a) rejection, and (2) the effectiveness of the first 35 U.S.C. § 103(a) rejection. Appellant submits that if Appellant's claimed invention would have been obvious in view of Warren alone, then the Examiner should not need to use Warren to support the second 35 U.S.C. § 103(a) rejection.

2. The Examiner's modifications of the devices disclosed by Warren and Bays is beyond what the disclosures of Warren and Bays contemplate.

Warren teaches that "the dimensions of the fastener could be changed so as to make the fastener longer and thinner, or shorter and fatter, etc." (Warren, col. 6, lines 47-49). Bays teaches that "variations from these dimensions are possible for different utilizations of tack member 10." (Bays, col. 7, lines 15-17). The Examiner focuses on these general statements as the reason for modifying the Warren fastener and Bays repair tack to fit within the scope of Appellant's claims. However, the Examiner's proposed modification of the Warren fastener and Bays repair tack oversteps the bounds of what the disclosure of either Warren or Bays contemplated in the design of

the respective inventions. Both Warren and Bays teach that their invention must have a structural rigidity to withstand the method of insertion taught by each reference. (See Appeal Brief, section V, sub-section A1 and section VI, sub-section A2). The structural rigidity necessary for the Warren and Bays inventions would not allow for the degree of flexibility recited in Appellant's claims.

II. Specific remarks in response to Examiner's Answer.

Appellant will address the Examiner's Answer in the order that the objections and rejections were presented in the Examiner's Answer using the section/sub-section numbering scheme applied in the Appeal Brief and referred to by the Examiner in the Examiner's Answer. The section/sub-section referred to in the body of each heading correspond to the section/sub-section in the Appeal Brief.

A. Section I, sub-section A of the Appeal Brief.

(I) Response to Examiner's "Grounds of Rejection."

The Examiner states that "Appellant is now relying patentability on limitation however, it is not clear from the specification what would comprehend this language." (Examiner's Answer, paragraph bridging pages 3-4). As set forth in the Appeal Brief, Appellant submits that the flexible member being at least in part curved when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. (See Appeal Brief, section A1). According to the MPEP, "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it." (MPEP § 2163.07(a), page 2100-184, col. 1 (May 2004)(emphasis added)).

The Examiner states that "[I]t is not clear how this would define over the art since the art teaches the same structure using the same material." (Examiner's Answer, paragraph bridging pages 3-4). The Examiner's statement concerning the prior art is misplaced as the consideration of prior art is an issue separate and distinct from the issue of whether an amendment contains new matter. Appellant's remarks addressing

the prior art are contained below under the sections dealing with the Examiner's prior art rejections.

(ii) Response to the Examiner's "Response to Argument."

The Examiner attempts to refute Appellant's arguments by discussing the present claims in view of the prior art. (Examiner's Answer, page 11, paragraph 1). Appellant submits that the Examiner's discussion has no bearing on whether the amendment filed January 7, 2004 (the "January 2004 Amendment") contains new matter.

B. Examiner's response to section I, sub-section B of the Appeal Brief.

The Examiner's remarks under the "Response to Argument" section again try to improperly combine issues of prior art with a new matter inquiry. Further, the Examiner's inquiries asking how the subject matter of claim 33 further limits the subject matter of claim 29 bear no relation to the issue of whether the January 2004 Amendment contains new matter. Nonetheless, Appellant submits that claim 33 further limits claim 29 because claim 33 recites a particular shape of the general curve recited in claim 29.

The Examiner states that "[t]he specification doesn't appear to provide such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." (Examiner's Answer, page 12, paragraph 2). Appellant respectfully submits that the Examiner's statement is improper because it does not indicate what portion of the specification is allegedly not enabling. Appellant traverses the Examiner's statement. Appellant submits that a person of ordinary skill in the art would be able to make and use Appellant's claimed invention upon reviewing Appellant's disclosure.

C. Examiner's response to section I, sub-section C of the Appeal Brief.

Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position on the Examiner's objection in view of the Examiner's Answer.

D. Examiner's response to section I, sub-section D of the Appeal Brief.

The Examiner is on record as stating that "the drawing may support that fact that the flexible member is smaller than the shaft." (Examiner's Answer, page 4, paragraph 3). MPEP § 2163(II)(A)(3)(a) states that "[a]n Applicant may show

possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Applicant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118, ("drawings alone may provide a 'written description' of an invention as required by sec. 112"). (MPEP § 2163(II)(A)(3)(a), page 2100-170, col. 2 to page 2100-171, col. 1 (May 2004)). Appellant submits that the Examiner's objection to the phrase "said flexible member has a smaller mass than the mass of said shaft" has been overcome in view of the Examiner's own remarks and by the fact that this feature is shown in the drawings.

The Examiner contends that the "function of being absorbed prior to the shaft so that the flexible member does not separate from the shaft is not fully understood because it is not disclosed." (Examiner's Answer, paragraph bridging pages 4-5). Appellant submits that the prior absorption of the flexible member is inherent as would be recognized by one of ordinary skill in the art because an object having a smaller mass will be absorbed sooner than an object of larger mass. According to the MPEP, "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it." (MPEP § 2163.07(a), page 2100-184, col. 1 (May 2004)) (emphasis added). By having a flexible member with a smaller mass, Appellant's invention has the advantage of preventing a premature disengagement of the flexible member relative to the tissue it contacts.

E. Remarks concerning section I, sub-section E of the Appeal Brief.

(i) Response to Examiner's "Grounds of Rejection."

Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position on the Examiner's new matter objection in view of the Examiner's Answer.

The Examiner's inquiries in the Examiner's Answer asking how the subject matter of claim 145 further limits the subject matter of claim 144 bear no relation to the issue of whether the January 2004 Amendment contains new matter. Nonetheless, Appellant submits that claim 145 further limits claim 144 because claim 145 recites that

a second portion of the flexible member forms an included angle less than 90 degrees. Claim 144 does not require an included angle less than 90 degrees.

For the Examiner's new matter objection to claim 144, Appellant submits that an included angle of greater than 90 degrees is supported at least by Fig. 7. (See Appeal Brief, Exhibit D, Fig. 7).

(ii) Response to Examiner's "Response to Argument."

Appellant respectfully disagrees with the Examiner's contention that claim 145 recites the second portion forming an included angle relative to the mid-longitudinal axis of the shaft that is greater than 90 degrees. Claim 145 recites the included angle formed by the second portion and the mid-longitudinal axis of the shaft as being less than 90 degrees.

Appellant further disagrees with the Examiner's contention that angular relationship recited in claim 145 is a positive structural limitation of the device before use. The Examiner is attempting to improperly read into the claim a temporal limitation that is not recited.

F. Examiner's response to section I, sub-section F of the Appeal Brief.

Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position on the Examiner's new matter objection in view of the Examiner's Answer.

G. Examiner's response to section I, sub-section G of the Appeal Brief.

Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position on the Examiner's new matter objection in view of the Examiner's Answer.

H. Examiner's response to section II of the Appeal Brief.

Appellant respectfully submits that the Examiner has failed to establish a *prima facie* case under 35 U.S.C. § 112, first paragraph, by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that Appellant was in possession of the invention as claimed in view of the disclosure of the application as filed. (See MPEP § 2163.02(III)(A)(B)). Appellant respectfully submits that the Examiner's remarks about criticality are not relevant to an inquiry under 35 U.S.C. § 112, first paragraph, for lack of written support.

I. Examiner's response to section III, sub-sections A-G of the Appeal Brief.

For claims 29-59, 65, 66, 100-143, 145, 148-150, 183-185, 211-241, 245-247, and 293-300, Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position in view of the Examiner's Answer.

For claims 60-64, 67-99, the Examiner contends that the phrase "said flexible member is deformable to have an at least in part concave shape" (objected to in section B of the rejection under 35 U.S.C. § 112, first paragraph; see section B of the objection under 35 U.S.C. § 132) is applicable to independent claim 60, which recites "said top of said flexible member being at least in part concave when said flexible member is in contact with the tissue." Appellant respectfully traverses the Examiner's contention. The phrase "said flexible member is deformable to have an at least in part concave shape" relates to the flexible member being deformable to have an at least in part concave shape. The scope of this phrase is different from the subject matter of independent claim 60. Accordingly, Appellant submits that the subject matter of claim 60 does not fall under section B of the rejection under 35 U.S.C. § 112, first paragraph.

For claims 144, 146, 147, and 151-175, the Examiner contends that "claim 144 recites at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees and therefore falls with paragraph e) above." (Examiner's Answer, page 14, paragraph 4). Appellant disagrees with the Examiner's contention. The phrase being objected to under section E of the objection under 35 U.S.C. § 132 recites "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees." (Examiner's Answer, page 3 paragraph 7 (emphasis added)). Independent claim 144 recites the included angle being greater than 90 degrees. Therefore, contrary to the Examiner's contention, independent claim 144 (and its dependent claims) do not fall under section E of the rejection under 35 U.S.C. § 112, first paragraph. The Examiner still has not provided any applicable rationale as to why claims 144, 146, 147, and 151-175 are rejected under 35 U.S.C. § 112, first paragraph.

Despite Appellant's remarks on pages 13-14 of the Appeal Brief that the Examiner had not provided any rationale as to why certain claims were rejected under

35 U.S.C. § 112, first paragraph, and the Examiner's acknowledgement of Appellant's remarks (see Examiner's Answer, page 14, paragraph 4), the Examiner still has not provided any rationale as to why claims 176-182, 186-210, 242-244, and 248-292 are rejected under 35 U.S.C. § 112, first paragraph. Accordingly, Appellant submits that the remarks pertaining to claims 176-182, 186-210, 242-244, and 248-292 stand unchallenged and that these claims are allowable despite the Examiner's *en masse* rejection of all claims.

J. Examiner's response to section IV of the Appeal Brief.

Appellant respectfully submits that the rejection under 35 U.S.C. § 112, second paragraph, is improper because the Examiner's rationale for supporting the rejection relates to issues of inadequate written support and not to indefiniteness, which is an issue under 35 U.S.C. § 112, first paragraph, not second paragraph. (See MPEP § 2173.04 "Breadth Is Not Indefiniteness," which recites that "[b]readth of a claim is not to be equated with indefiniteness." *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971) (MPEP § 2173.04 (May 2004)).

K. Examiner's response to section IV, sub-sections A-C of the Appeal Brief.

In the Examiner's Answer, the Examiner states that Appellant's arguments with respect to section IV, sub-sections A-C "are moot in view of the amendment entered in 20 September 2004." (Examiner's Amendment, page 16, paragraph 1). Appellant understands the Examiner's remarks to indicate that the rejection of the claims specific to the reasons set forth in section IV, sub-sections A-C of the Appeal Brief have been overcome by the amendment of September 20, 2004.

For the rejection of the claims specific to the reasons set forth in section IV, sub-section D, Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position in view of the Examiner's Answer.

For claims 60-99, 144, 146, 147, 149-155, 157, 159-172, 174, and 175, Appellant submits that the Examiner's rejection of these claims are overcome based on Appellant's remarks above addressing the Examiner's rejection of these claims under 35 U.S.C. § 112, first paragraph, these remarks being incorporated by reference herein. (See section II, sub-section I of the present Reply Brief above).

For the rejection of claims 176-182, 186-210, 242-244, and 248-292 under 35 U.S.C. § 112, second paragraph, the Examiner fails to address why these claims lack support under 35 U.S.C. § 112, first paragraph. Appellant submits that this is applicable to the present rejection as the Examiner's basis for the rejection of claims 29-300 is lack of support. Accordingly, Appellant submits that the remarks pertaining to claims 176-182, 186-210, 242-244, and 248-292 stand unchallenged and that these claims are allowable despite the Examiner's *en masse* rejection of all claims.

L. Examiner's response to section V, sub-section A1 of the Appeal Brief.

The Examiner contends that "this limitation [flexible member being curved when in contact with the tissue] is also contingent on whether or not the rivet is being inserted at an angle to the tissue surface. Plus this limitation is also contingent on whether or not the rivet is being inserted at an angle to the tissue surface." (Examiner's Answer, page 16, paragraph 2). Appellant respectfully disagrees with the Examiner's contention. Appellant respectfully submits that the Examiner is reading issues pertaining to lack of support in the specification into the art rejection. Appellant respectfully submits that the proper question to be asked by the Examiner is whether the "prior art structure is capable of performing the intended use." (MPEP § 2111.02, citing *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997)). Although *In re Schreiber* applied this question relative to the preamble of a claim, Appellant submits that the question is equally applicable to the body of the claim.

The fastener of Warren is structurally incapable of flexing to the degree required by Appellant's claims. The Examiner contends that "the dimensions of the fastener can be changed to make the fastener thinner or thicker. It can be longer or shorter. Warren is not limited to just the embodiment shown in the drawings. Finding the optimum dimensions and characteristics for a specific intended use would be well within the realm of the artisan of ordinary skill." (Examiner's Answer, page 17, paragraph 1). Appellant submits that Warren may be slightly modified, but not to such an extent as contended by the Examiner that would go beyond or contravene the teachings of Warren. Warren teaches that the structure of the fastener must be strong enough to withstand repeated blows to drive it into the tissue. Warren accomplishes this in at least two ways. First, the head is made sufficiently thick to withstand the repeated

blows. Secondly, Warren incorporates a fillet 161 to strengthen the head. This structural teaching is counter to making the head flexible.

Appellant disagrees with the Examiner's contention that "making the head of the fastener less obtrusive so that it is flush with the tissue surface is a well-recognized problem in the art." (Examiner's Answer, page 17, paragraph 1). The Examiner has presented no evidence to support his contention. Moreover, the primary references asserted by the Examiner, Warren and Bays, each disclose heads that are purposely designed to be thick in order to withstand the insertion forces. Modifying the head of the Warren fastener to be thinner to be less obtrusive so as to be flush would be counter to the teachings of Warren.

Appellant also respectfully disagrees with the Examiner's contention that "there doesn't appear to be unexpected results which is different in kind and not merely in degree from the results of the prior art." (Examiner's Answer, page 17, paragraph 2). One result that is superior to that obtained by Warren is that Appellant's tissue rivet as claimed will cause less trauma to the surrounding tissue due at least to the flexibility or angular orientation of the member relative to the shaft.

M. Examiner's response to section V, sub-section A2 of the Appeal Brief.

In the Examiner's Answer, the Examiner asks "[I]f the prior art and the instant Invention are intended for the same purpose then how is it different?" (Examiner's Answer, page 18, paragraph 1). At least one difference between the tissue rivet of the present invention and the fastener of Warren is that Appellant's tissue rivet has a head structure that can be at an angle once the rivet is fully inserted. The fastener of Warren is configured so that the head structure is always perpendicular to the shank, no matter what angle the Warren fastener is inserted.

The Examiner states that in Appellant's specification, the rivet is "driven into place somehow." (Examiner's Answer, page 18, paragraph 1). As disclosed by Appellant, a shaft 132 of driver 130 is "passed through the passageway 124 in the rivet 100 until the rear 120 of the disc 118 abuts the flat face 135 of the handle 131. (Specification, page 7, lines 21-23; Fig. 5). Once the driver is engaged to the rivet, "the shaft 132 of the driver 130 with the rivet 100 in place is then pushed thought the meniscus M until the tear T is compressed." (Specification, page 7, lines 27-29;

Figs. 6-7 (emphasis added)). Accordingly, the way in which the fastener of Warren and the rivet of the present invention are inserted is quite different.

The Examiner's statement that "[t]he prior art is also driven into place using the same type of driver" is not correct. (Examiner's Answer, page 18, paragraph 1). Warren teaches using a hollow driver 600 that slides over a guide wire 400 to pound fastener 100 into place. (Warren, col. 5, lines 8-16; Figs. 6-7). The driver disclosed by Appellant is a single, unitary structure having a shaft 132 integrally connected with a handle 131. A guide wire is not necessary to drive the rivet of Appellant's claimed invention. Contrary to the Examiner's contention, the Warren fastener is not driven into place "using the same type of driver."

N. Examiner's response to section V, sub-section A3 of the Appeal Brief.

The Examiner states that the thickness of the head of the Warren fastener would allow it to be flexible and that "[t]his inherent flexibility would comprehend the claim language." (Examiner's Answer, page 18, paragraph 2). According to the Federal Circuit,

"[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'"

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Moreover, according to precedent established by the Board, "[I]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (*Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis in original)).

As set forth above, Warren teaches at least two ways in which the fastener is structurally configured to resist flexibility. First, the head is made sufficiently thick to withstand the repeated blows. Secondly, Warren incorporates a fillet 161 to strengthen the head. This structural teaching is counter to making the head flexible. Accordingly, Appellant submits that a person of ordinary skill in the art would not recognize the inherency that the Examiner is seeking to establish.

The Examiner states that "Warren teaches that the dimensions of the fastener can be changed as desired." (Examiner's Answer, page 18, paragraph 2). Warren may teach that the dimensions may be modified, but such modifications must still exist within the general teachings of Warren, otherwise the fastener would be rendered unsuitable for its intended purpose of being able to be pounded into bone as taught by Warren. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-131, col. 2 (May 2004)).

O. Examiner's response to section V, sub-section A4 of the Appeal Brief.

Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position on the Examiner's use of impermissible hindsight in view of the Examiner's Answer.

P. Examiner's response to section V, sub-section B1 of the Appeal Brief.

The Examiner contends that the driver disclosed by Warren "provides the required structural rigidity to facilitate driving and inserting the fastener into bone." (Examiner's Answer, page 19, paragraph 2). The Examiner attempts to support his contention by making another contention, that "the shaft of the driver received within the hollow shank of the fastener also provides the required structural rigidity to the shank to maintain the integrity of the shank to drive the fastener into the bone." (Examiner's Answer, page 19, paragraph 2). The Examiner's contentions are incorrect. As set forth above, Warren does not teach a driver having a shaft, but a hollow driver 600 in combination with a guide wire 400. (Warren, col. 5, lines 8-16; Figs. 6-7). Hollow driver 600 is in moveable relationship with guide wire 400. Driver 600 is used to "repeatedly strike fastener 100 on its upper surface 150." (Warren, col. 5, lines 11-12). If the head of the Warren fastener were modified as suggested by the Examiner, then striking the upper surface of the modified fastener with driver 600 would likely destroy the fastener as the head would have insufficient rigidity to transfer the force from the repeated blows to move the fastener down the guide wire.

The Examiner's contention that "[i]f Appellant's arguments were true the Appellant's invention wouldn't work either because the instant invention is also intended to be inserted into bone just as Warren's" ignores the different manners in which the tissue rivet of the presently claimed invention and the fastener of Warren are inserted.

Warren teaches a configuration of a fastener that is suited for the manner in which it is inserted, and is different than the way in which the rivet of the presently claimed invention is inserted.

Q. Examiner's response to section V, sub-sections B2, B4, and B6 of the Appeal Brief.

The Examiner contends that Warren teaches a beveled outer edge. (Examiner's Answer, page 20, paragraph 1). Appellant respectfully disagrees with the Examiner's contention. According to the Dictionary, the term "beveled" means "to cut or shape to a bevel." (Merriam-Webster's Collegiate Dictionary, 10th ed., page 109 (1999)). The term "bevel" means "the angle that one surface or line makes with another when they are not at right angles." (Merriam-Webster's Collegiate Dictionary, 10th ed., page 109 (1999)). Warren teaches a head 110 that has a rounded edge at top surface 150. (Warren, Fig. 1). The rounded edge of the fastener head shown in Fig. 1 of Warren is not a bevel.

R. Examiner's response to section V, sub-sections B3, B5, B7, B8, B10, and B11 of the Appeal Brief.

For the Examiner's response to Appellant's remarks in section V, sub-sections B3, B5, B7, B8, B10, and B11, Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position in view of the Examiner's Answer.

S. Examiner's response to section V, sub-sections B12-B14 of the Appeal Brief.

For the Examiner's response to Appellant's remarks in section V, sub-sections B12-B14, independent claims 273, 283, and 293 are method claims. Even, *assuming arguendo*, the Examiner could modify the fastener of Warren to come within the scope of Appellant's apparatus claims, the Examiner has not provided any motivation for modifying the method taught by Warren to come within the scope of Appellant's method claims. (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)).

T. Examiner's response to section V, sub-section B9 of the Appeal Brief.

For the Examiner's response to Appellant's remarks in section V, sub-section B9, the Examiner has not provided any motivation for combining the teachings of Warren and Duncan. Moreover, Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's

Collegiate Dictionary defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 192 is allowable over the combination of Warren in view of Duncan.

U. Examiner's response to section VI, sub-section A1 of the Appeal Brief.

The Examiner states that "[t]he prior art teaches the motivation for modifying the dimensions of the rivet" and that "Bays teaches '[i]t is to be understood, of course, that variations from these dimensions are possible for different utilizations of tack member 10.'" (Examiner's Answer, paragraph bridging pages 20-21). The text quoted by the Examiner is the type of general language that many patent applications contain and is usually intended as a statement that the invention may be modified within the scope of the teachings of a given application. The modification proposed by the Examiner exceeds the teachings of Bays and Warren in that it requires the head of the rivet to be more flexible to such an extent that the rivet would no longer be insertable using the methods taught by Bays and Warren. Accordingly, Appellant submits that the Examiner's proposed modification of the repair tack of Bays is counter to the teachings of Bays and Warren.

The Examiner asks the question "[h]ow thin does the head have to be to anticipate the claimed invention?" (Examiner's Answer, page 21, paragraph 1). Appellant submits that the Examiner's focus is aimed solely at the thinness of the head rather than the entire structure of the rivet. For example only, part of the reason that the head of Warren is not flexible (i.e., maintains a perpendicular profile relative to the shank) is that the Warren fastener includes a fillet 161 to strengthen the juncture between the head and the shank. (Warren, col. 3, lines 40-42; Fig. 1).

V. Examiner's response to section VI, sub-section A2 of the Appeal Brief.

The Examiner states "[r]egarding Appellant's arguments in paragraph VI A2, it is not clear how much weight can be given the arguments that the applicator 20 of Bays must be sufficiently rigid enough to withstand axial movement and withstand twisting or rotation. This has nothing to do with the rejection." (Examiner's Answer, page 21, paragraph 2). Appellant respectfully submits that the Examiner has misread Appellant's

arguments under section VI, sub-section A2. Appellant states that "[i]n order to serve its intended purpose, the head portion adapted to be used with the applicator of Bays must be sufficiently rigid enough to withstand axial movement and withstand twisting or rotation." (Appeal Brief, page 32, section VI, sub-section A2 (emphasis added)). Appellant's remarks refer to the head portion of the rivet.

The Examiner further states that "if it is felt that the rivet of Bays somehow does not deform then Warren additionally is cited to teach the convention of being able to change the relative dimensions of the rivet dependent on practical considerations of intended use." (Examiner's Answer, page 21, paragraph 2). Appellant submits that the Examiner is ignoring the "practical considerations of intended use" contemplated by Bays and Warren. A fastener head that is rigid enough to withstand axial movement and twisting or rotation about any vertical axis, such as taught by Bays and Warren, cannot be fairly said to be sufficiently flexible within the scope of Appellant's claimed invention. If the Examiner were to modify the repair tack of Bays or the fastener of Warren to have a head that is flexible within the scope of Appellant's claimed invention, then such a modification would require a completely new tool and method not contemplated by either Bays or Warren in order to insert such a device.

W. Examiner's response to section VI, sub-section B1 of the Appeal Brief.

The Examiner statement that "the heads of Bays and Warren can withstand being inserted by the insertion tool because the insertion tool contacts and holds the head of the fastener firmly in place and transfers the forces directly to the shaft of the fastener just as Appellant's invention does" is not correct. (Examiner's Answer, page 21, paragraph 3). Both Bays and Warren each teach a two-piece insertion device having a portion that separately applies a force on the head portion of the rivet. (See, e.g., Bays, col. 6, lines 41-43, Figs. 1-2; Warren, col. 5, lines 8-16; Figs. 6-7). As would be appreciated by one of ordinary skill in the art, separately applying a force on the head and the shaft creates stress at the junction of the head portion and the shaft. That is why the repair tack of Bays and the fastener of Warren are configured so that the respective head portions are rigid. The driver disclosed by Appellant is a single, unitary structure having a shaft 132 integrally connected with a handle 131. Because of the unitary structure of Appellant's driver, there are not separate forces emanating from

different portions of the insertion tool assembly acting on the flexible member and the shaft. Accordingly, the flexible member taught by Appellant is configured to be flexible within the scope of Appellant's claims and may be inserted into tissue without destroying the rivet.

X. Examiner's response to section VI, sub-sections B2, B4, and B6 of the Appeal Brief.

For the Examiner's response to Appellant's remarks in section VI, sub-sections B2, B4, and B6, Appellant incorporates the remarks from section II, sub-section Q above (pertaining to section V, sub-sections B2, B4, and B6 of the Appeal Brief). Moreover, Appellant submits that each of the claims or groups of claims argued in each of the sub-sections are separately patentable for the reasons provided in the Appeal Brief.

Y. Examiner's response to section VI, sub-sections B3, B5, and B7-B10 of the Appeal Brief.

For the Examiner's response to Appellant's remarks in section VI, sub-sections B3, B5, and B7-B10, Appellant incorporates the remarks from section II, sub-section U above (pertaining to section VI, sub-section A1 of the Appeal Brief). Moreover, Appellant submits that each of the claims or groups of claims argued in each of the sub-sections are separately patentable for the reasons provided in the Appeal Brief.

Z. Examiner's response to section VI, sub-sections B11, B14, and B18 of the Appeal Brief.

For the Examiner's response to Appellant's remarks in section VI, sub-sections B11, B14, and B18, independent claims 273, 283, and 293 are method claims. Even, *assuming arguendo*, the Examiner could modify the repair tack of Bays in view of Warren to come within the scope of Appellant's apparatus claims, the Examiner has not provided any motivation for modifying the method taught by either Bays or Warren to come within the scope of Appellant's method claims. (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Moreover, Appellant submits that each of the claims or groups of claims argued in each of the sub-sections are separately patentable for the reasons provided in the Appeal Brief.

AA. Examiner's response to section VI, sub-sections B12, B15, and B19 of the Appeal Brief.

The Examiner contends that Appellant is disregarding the teaching of the prior art. (Examiner's Answer, page 22, paragraph 3). Appellant respectfully submits that the Examiner has not considered the entire claim, or all of Appellant's remarks from the Appeal Brief. In the Appeal Brief, Appellant stated that none of the art, whether alone or in proper combination, teach or suggest the step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. (Appeal Brief, pages 36-38, section VI, sub-sections B12, B15, and B19 (emphasis added)). As neither Bays nor Warren teach providing a driving instrument having a shaft extending from a handle (as recited in claims 277, 286, and 295), it then follows that neither Bays nor Warren teach step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member.

Moreover, Appellant submits that each of the claims or groups of claims argued in each of the sub-sections are separately patentable for the reasons provided in the Appeal Brief.

BB. Examiner's response to section VI, sub-sections B13, B17, and B20 of the Appeal Brief.

The Examiner states that "attaching the meniscus to the bone isn't always inserting the leading end of the shaft toward the center of the knee. Repairing torn meniscus is never always going to be directed toward the center of the knee." (Examiner's Answer, page 22, paragraph 4). Appellant submits that the Examiner's remarks are superfluous to the rejection at hand. They do not address the subject matter of any of claims 281, 291, and 299, nor do they explain how the subject matter of these claims are somehow obvious in view of the cited art.

Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position in view of the Examiner's Answer. Moreover, Appellant submits that each of the claims or groups of claims argued in each of the sub-sections are separately patentable for the reasons provided in the Appeal Brief.

CC. Examiner's response to section VI, sub-section B16 of the Appeal Brief.

The Examiner states that "[t]here is no unobviousness to the head being friction fit or snap fit in place. Such is well within the realm of the artisan of ordinary skill." (Examiner's Answer, page 22, paragraph 5). Appellant respectfully disagrees with the Examiner's contentions. Snap-fitting the rivet onto a portion of the driving instrument provides for increased securement as opposed to a simple friction-fit securement. Moreover, the Examiner has not indicated how Bays would be modified to accommodate a snap-fit securement. Appellant submits that the Examiner has failed to provide any rationale as to why a person of ordinary skill in the art would have considered it obvious to modify Bays for a snap-fit engagement between the driver and repair tack.

DD. Examiner's response to remarks at the end of section VI concerning claims 277, 286-288, and 295 of the Appeal Brief.

The Examiner contends that "the rivet passageway cooperating with the shaft extending from the handle of the insertion instrument is clearly taught by both Bays and Warren." (Examiner's Answer, page 22, paragraph 6). Appellant respectfully disagrees with the Examiner's contention. Bays and Warren teach two-piece insertion assemblies. Neither Bays nor Warren teach or suggest, whether alone or in proper combination, a driving instrument with a handle, a shaft extending from the handle, and a face at a junction of the handle and the shaft as recited in claims 277, 286, and 295. (See, e.g., Bays, applicator 20 and needle 30, Figs. 1-2; Warren, driver 600 and guide wire 400, Figs. 6-7).

Moreover, neither Bays nor Warren teach or suggest, whether alone or in proper combination, the step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. Bays teaches first engaging applicator 20 to repair tack 10. Once applicator 20 is engaged with the repair tack, "[n]eedle 30 is then slidably passed through the hollow applicator and bore 13 in tack member 10." (Bays, col. 6, lines 25-30). Warren teaches loading fastener 100 onto guide wire 400, then coaxially fitting hollow driver 600 onto the guide wire. (Warren, col. 4, lines 49-50 and col. 5, lines 8-11). Thus, in

the method taught by Warren, fastener 100 is fully inserted over guide wire 400 before the driver contacts the fastener. (See Warren, Fig. 6).

EE. Examiner's response to section VII, sub-section A of the Appeal Brief.

Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position on the Examiner's objection in view of the Examiner's Answer.

Appellant submits that contrary to the Examiner's contention, a person of ordinary skill in the surgical field would not look to the automotive field for rivets to arrive at Appellant's claimed invention.

FF. Examiner's response to section VII, sub-sections B1-B7 of the Appeal Brief.

Appellant respectfully disagrees with the Examiner's contention that "Duncan teaches projections that are in staggered overlapping configuration." (Examiner's Answer, page 23, paragraph 3). Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Moreover, Appellant submits that each of the claims or groups of claims argued in each of the sub-sections are separately patentable for the reasons provided in the Appeal Brief.

GG. Examiner's response to section VIII, sub-section A of the Appeal Brief.

The Examiner states that "[i]n the art of engaging the driver to the head of the fastener one would look to equivalent driver and fastener engagement means. Simmons exemplifies an obvious equivalent." (Examiner's Answer, paragraph bridging pages 23-24). Appellant submits that the Examiner's reliance on Simmons being an obvious equivalent is improper. According to the MPEP, "[i]n order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on Appellant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents." (MPEP § 2144.06, page 2100-144, cols. 1 and 2 (May 2004), citing *In re Ruff*, 256 F.2d 590 (CCPA 1958)).

Since Simmons fails to teach that his driver head is equivalent to the applicator configuration taught by Bays, the driver taught by Simmons cannot be cited as an obvious equivalent.

HH. Examiner's response to section VIII, sub-sections 31-B4 of the Appeal Brief.

Appellant submits that the remarks contained in the Appeal Brief adequately state Appellant's position in view of the Examiner's Answer. Moreover, Appellant notes that the Examiner did not present any arguments refuting Appellant's position as stated in the Appeal Brief. Accordingly, Appellant's position stands unchallenged.

III. Conclusion.

For the foregoing reasons and the reasons set forth in the Appeal Brief, Appellant submits that: (1) the amendment filed January 7, 2004 does not introduce new matter into the specification; (2) the specification supports the invention as now claimed; (3) the claims comply with the written description requirement under 35 U.S.C. § 112, first paragraph; (4) the claims are definite; (5) the Examiner's rejection under 35 U.S.C. § 103(a) in view of Warren has been overcome; (6) the Examiner's rejection under 35 U.S.C. § 103(a) in view of Bays and Warren has been overcome; (7) the Examiner's rejection under 35 U.S.C. § 103(a) in view of Bays and Warren, further in view of Duncan, Chisholm, or Paravano has been overcome; and (8) the Examiner's rejection under 35 U.S.C. § 103(a) in view of Bays, Warren, Duncan, Chisholm, or Paravano, further in view of Simons has been overcome.

Appellant submits that the claims are supported at least by the drawings. Further, Appellant submits that the Examiner's attempted redesign of the fastener of Warren and the repair tack of Bays extends beyond what either of the disclosures of Warren and Bays contemplated and would render the respective inventions inoperable for the intended purpose as taught in each of Warren and Bays. Accordingly, Appellant respectfully requests the Board to reverse all of the Examiner's objections and rejections stated in the Examiner's Answer.

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136,

please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted.

MARTIN & FERRARO, LLP

Dated: September 1, 2005

By: Todd M. Martin

Todd M. Martin

Registration No. 42,844

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (330) 877-0700
Facsimile: (330) 877-2030